

**Application No.:** 10/537,839  
**Filing Date:** May 18, 2006

## **REMARKS**

The Specification is amended by identifying peptide and nucleotide sequences with SEQ ID NO identifiers and embedded hyperlinks are removed. A substitute Sequence Listing is submitted herewith. Claims 57-65 are presently pending. Support for amendments to Claim 57 can be found in the Specification as filed, for example at page 17, line 3 and at page 19, lines 8 to 15. No new matter has been added herewith. The following addresses the substance of the Office Action.

### **Indefiniteness**

Claims 57-61 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. The examiner alleged that the claims were indefinite as a result of the phrase "the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO: 4 or an amino acid sequence having at least 90% identity thereto". It was not clear to the Examiner how a nucleotide sequence could be 90% identical to an amino acid sequence. The Applicants have amended Claim 61 by explicitly stating "...an amino acid sequence having at least 95% identity to the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO:4." The Applicants have also amended Claim 61 by adding the phrase "or a protein encoded by a nucleotide sequence that hybridizes to the polynucleotide of SEQ ID NO: 4 under high stringency conditions." Support for this amendment can be found in the specification as filed, for example at page 17, line 3 and at page 19, lines 8 to 15. In view of these amendments, the Applicants respectfully request removal of the rejection.

### **Written Description**

Claims 57-61 were rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The examiner confirms that a nucleotide sequence having SEQ ID NO: 4 meets the written description requirement, but alleges that the specification provides insufficient description of sequences having at least 90% sequence identity to the protein encoded by SEQ ID NO: 4.

The Applicants have amended Claim 57 to recite "...an amino acid sequence having at least 95% identity to the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO:4." Referring to Example 10 of the United States Patent and Trademark Office Written

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Description Training Materials, Revision 1, dated March 25, 2008, those of skill in the art could readily envision all of the amino acid sequences that are 95% identical to the amino acid encoded by SEQ ID NO: 4. Those skilled in the art could recognize amino acid sequences that are 95% identical to the amino acid encoded by SEQ ID NO: 4 by comparing a given sequence to the amino acid sequence encoded by SEQ ID NO: 4. The level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify amino acid sequence variants having 95% identity to the amino acid encoded by SEQ ID NO: 4 routinely.

The Applicants note that the Specification discloses in Table 4 that SEQ ID NO: 4 provides the human DCL-1 cDNA sequence. Other DCL-1 sequences are also provided, see SEQ ID NOs: 7 and 10 which respectively provide the mouse and rat DCL-1 cDNA sequences. Moreover, page 67, lines 16-18 of the specification discloses that "DCL-1 is highly conserved between species. For example, it is approximately 80% conserved between mouse and humans." To elaborate, the amino acid sequence of rat DCL-1 is 81% identical to human and 92% identical to mouse. The cDNA sequence of rat DCL-1 is 81% identical to human and 90% identical to mouse. Furthermore, the mouse cDNA sequence of DCL-1 is 85% identical to human.

Referring to the Specification at page 51, line 28 through page 52, line 27, there is written support for polyclonal and monoclonal antibodies to DEC-205 SV or DCL-1 proteins, which include sequences from e.g., human, mouse and rat. Support for an amino acid sequence having at least 95% identity to SEQ ID NO: 4 can be found at page 17, line 3 of the Specification. In view of the amendment to the claims and the preceding remarks, the Applicants request removal of the written description rejection under 35 U.S.C. § 112, first paragraph.

### **Enablement**

Claims 57-61 were rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an antibody that specifically binds to the polypeptide encoded by the polynucleotide of SEQ ID NO: 4, allegedly does not reasonably provide enablement for an antibody that specifically binds to an amino acid sequence having 90% identity to the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO: 4.

The examiner has confirmed that the specification is enabled for an antibody that specifically binds to the polypeptide encoded by SEQ ID NO: 4. As discussed above, the Applicants have amended Claim 57 to recite "...an amino acid sequence having at least 95%

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identity to the amino acid sequence encoded by the polynucleotide sequence of SEQ ID NO:4.” The Applicants note the passage at page 52, lines 19-21 of the specification, which discloses that methods of producing monoclonal and polyclonal antibodies are well known in the art. A specific method of producing a monoclonal antibody is provided at page 59, line 24 of the specification. Generating and screening of monoclonal antibodies is a routine procedure, even though considerable experimental work may be required to ultimately obtain the desired antibodies. In light of the amendments to the claims and the preceding remarks, the Applicants respectfully request removal of the enablement rejection under 35 U.S.C. § 112, first paragraph.

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

*Co-Pending Applications of Assignee*

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/888,911	DCL-1 AND USES THEREOF	July 31, 2007

**CONCLUSION**

In view of Applicants' amendments to the Specification and the Claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of

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the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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